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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,486	05/11/2005	Takanori Matsuo	10525.0015-00000	7810

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,486	MATSUO ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,34 and 35* is/are pending in the application.

4a) Of the above claim(s) *1-8,10-12,19-31,34 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *9 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/11/05, 1/3/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group III filed 2/08/08, is acknowledged.

Claims 1-8, 10-12, 19-31, 34, and 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 9 and 13-18 are under examination.

2. The Title is objected to because it does not accurately describe the claimed invention. Correction is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, specifically, the claim depends from Claim 7, which recites "comparing the activities of proteins", and Claim 7 depends from Claim 1, which recites "using said protein", whereas Claim 9 recites a method of "comparing the expressions of said gene". Accordingly, it is unclear how the method of Claim 9 can depend from the methods of Claims 1 and 7, thus, the metes and bounds of the claim cannot be determined. Further regarding Claim 9, the method comprises only "a screening method", i.e., the method has no purpose. Accordingly, the method is considered to be vague and indefinite.

5. Claims 19 and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01:

A) Regarding Claims 9 and 18, the method comprises only the cultivating of a cell and the comparing of the expressions of a gene (Claim 9) or comparing amounts of mRNA (Claim 18). The claims fail to recite what the comparison will tell the skilled artisan, and in the case of Claim 18, how said comparison will result in a prophylactic or therapeutic substance.

B) Regarding Claims 13-17, the method comprises a screening method for a prophylactic or therapeutic substance comprising

"using" a polynucleotide encoding SEQ ID NO:2 but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 13-17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). In particular, the claims recite neither a process, machine, manufacture, nor a composition as is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 9 and 13-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of:

A) "a disease associated with a protein comprising the same or substantially the same amino acid sequence as the amino acid sequence shown by SEQ ID NO:2 or a salt thereof", except diabetes (Claims 1, 13, and 14), or

B) "a gene whose expression is controlled by a protein comprising the same or substantially the same amino acid sequence as the amino acid sequence shown by SEQ ID NO:2 or a partial peptide thereof or a salt thereof, except insulin (Claim 9).

Regarding A), a review of the specification discloses no diseases associated with a protein comprising the same or substantially the same amino acid sequence as the amino acid sequence shown by SEQ ID NO:2 or a salt thereof, except possibly diabetes. A laundry list of diseases ranging from renal cancer to osteoporosis are disclosed as "characterized by an increased amount of the protein of the present invention" (pages 30-31), while a shorter list of diseases ranging from ulcers to brain tumors are disclosed as "characterized by a decreased amount of the protein of the present invention" (page 31), but no evidence is provided disclosing how these unrelated diseases are "associated" with the protein of SEQ ID NO:2. Absent a common structure and function relating the diseases, which has not been established, one of skill in the art would conclude that the specification fails to adequately describe the claimed genus of diseases.

Regarding B) a review of the specification discloses "the insulin gene and the like" (page 32) as genes whose expression is controlled by a protein comprising the same or substantially the same amino acid sequence as the amino acid sequence shown by SEQ ID NO:2. As genes comprising "the like" are not disclosed, it appears that the specification discloses just a single species to represent the entire claimed genus of genes. Accordingly, an adequate written description would require a disclosure of a common structure and function for the claimed genus of genes. As the only disclosed common function is the "control" of a protein, and no common structure is disclosed, one of skill in the art would conclude that the specification fails to adequately describe the claimed genus of genes. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 9 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,165,733 in view of Ihara et al. (2001).

The '733 patent teaches a screening method for a therapeutic substance (a mitogenesis inhibitor) comprising cultivating a cell (the contacted cell had to have been "cultivated") and comparing the expression of a gene in the presence or absence of a test compound (see particularly Claims 1 and 2). While the reference does not specifically teach the comparison of mRNA expression of Claim 18, comparisons of gene expression comprise either comparisons of DNA or mRNA expression such that either are readily envisioned as equivalents.

The reference differs from the claimed invention in that it does not teach comparing the expression of a gene encoding the protein of SEQ ID NO:2.

Ihara et al. teaches the protein of SEQ ID NO:2 (TSC-22), is associated with diabetes. In particular, the expression of the gene of SEQ ID NO:1 can be used as a marker for insulin expression. TSC-22 inhibits insulin expression such that a measure of TSC-22 expression can be used as a measure of insulin expression and the reduction of TSC-22 expression is an indication of increased insulin expression (see the entire Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the screening method of the '733 patent employing the measuring of the expression of the TSC-22 gene of Ihara et al. given the relationship of TSC-22 expression and insulin expression. Said method could be used as a method for screening test substances for their effect on TSC-22 expression as a measure of their efficacy as a therapeutic for the treatment of diabetes.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0878.

14. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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